REMARKS

Status of Claims

Claims 1 – 36 were original in the application. Claims 3, 5, 12-14, 18, 20, 27, 38 and 39 have been canceled. Claims 1, 4, 6, 10, 19, 22, 23, 33, 34, 37, and 40 are amended by the present amendment. Claims 1, 2, 4, 6 – 11, 15 – 17, 19, 21 – 26, 28 - 37 and 40 are submitted for substantive examination.

By way of preface it should be understood that the invention is particularly designed to successfully treat a form of brain cancer which responds to long term PDT. Repeated PDT treatments over an extended period of time, from a month up to a year are required in order to be effective. The problem was to find an implant system and methodology by which this type of treatment could be practically and successfully implemented. No available system existed prior to the invention.

Rejection Pursuant to 35 USC 103(a)

Claims 1 – 4, 6 – 11, 15 – 17, 19 and 21 were rejected as obvious over **Dietrich** in combination with **Chen** and **Lee**, *"Splittable Hemostatic Valve and Sheath and Method of Using the Same,"* U.S. Patent 5,125,904 (1992). **Dietrich** and **Chen** were previously cited in the prosecution. **Lee** is a new reference.

Dietrich shows an optical fiber being inserted into an implanted balloon in the embodiment of Fig. 2 for the purpose of uniform exposure for PDT. **Dietrich** was used to treat bladder cancer in which the inner walls of the bladder were irradiated and the natural channel of the urethra used for nontraumatic access. If used for other tissue sites which do no allow access through a natural body channel opening to the outside, each time that

the tissue is to be irradiated, it is necessary to invasively insert catheter 5 into the tissue or alternatively to leave catheter 5 implanted in the tissue at all times. Again, in a general tissue access, the proximal end of catheter 5 will extend from the body through the skin in all disclosed embodiments and is coupled to an external laser 21 or light source 9.

The Examiner should note that **Dietrich** does not disclose an ambulatory device, because there is no disclosure that the catheter implant is an entirely percutaneously implanted system. In the case where treatments must occur over the span of a month or a year, the **Dietrich** is impractical for this reason. The patient cannot be safely maintained with a catheter inserted into his brain and extending out of his head. The risk of injury or infection is too great to allow the patient out of confined and controlled hospital conditions with the system of **Dietrich**.

Thus, there is no teaching in **Dietrich,** which would allow post-implant, repeated, and nontraumatic treatments using an entirely percutaneously, invasively implanted system which is ambulatory. **Dietrich** cannot be used to practically and successfully treat the subject brain cancer.

Chen teaches the use of an implanted PDT device with inductively or battery powered LED's in the embodiments of Figs. 2A and 2B. The use of LED's is unacceptable in the case of brain tumor treatments due the heat, which would be generated in the brain tissue. Heat is generated not only by the light, but by the operation of the LED's which are never 100% efficient. Nevertheless, in the system of Figs. 2A and 2B of **Chen**, all the heat is ultimately delivered to the tissue whether in the form of light or ohmic heating in the LED's. While **Chen** explicitly regards such hyperthermia as

beneficial in connection with cancer treatments, (see Col. 3, lines 6 – 27) such may not be the case when neurological or brain tissues are concerned.

Further, the limitation of thermal load and power output from the LED's limits the type of PDT treatments which can be delivered and provides no means for varying frequencies or pulsing as is case with an external light or laser source. The use of fiber optic delivery insures that all the energy delivered to the treatment sight is in the form of light and there is no extra thermal burden. Fig. 2C of shows **Chen's** solution to the situation where an external light or laser source is used, namely the direct insertion of a catheter 44' carrying an optical fiber. The system of Fig. 2C is cumulative to **Dietrich.** When it comes to using an external laser, **Chen** has no new solution to the problem and simply reasserts **Dietrich's** approach.

Thus, like **Dietrich** there is no teaching in **Chen,** which would allow post-implant, repeated, and nontraumatic treatments using an external light source and an entirely percutaneously, invasively implanted system which is ambulatory. **Chen** cannot be used to practically and successfully treat the subject brain cancer.

Lee teaches the use of a hemostatic valve through which cardiac pacing leads are inserted and withdrawn through a self-healing membrane. **Lee** is not a percutaneously implanted system, but a valved introducer for implanting pacing leads into the heart. With the exception of the introducer **Lee's** device is used entirely outside the body in the hands of the surgeon.[1] The purpose of the **Lee** device is to avoid air embolism caused by suction of air into the vascular system when penetrated by an introducer for the purpose of implanting pacing leads into the heart through the subclavian vein. **Lee** has nothing to do with a system to allow post-implant, repeated, and nontraumatic treatments using an

external light source and an entirely percutaneously, invasively implanted system which is ambulatory.

The Examiner argues that **Dietrich** could be modified by taking the laser fiber optic system of **Chen** and inserting it through the membrane of **Lee**. None of these three references are directed to the solution of providing a practical and successful PDT system for long term, repetitive treatment of brain cancers, and being individually devoid of an relevant motivation or teaching their combination also fails to motivate the claimed combination. **Chen's** fiber optic in Fig. 2C is itself implanted and is not shown as repeatedly, and nontraumatically inserted into an entirely percutaneously invasively implanted system for use with an external light source. **Dietrich's** fiber optic is itself implanted and is not shown as repeatedly, and nontraumatically inserted into an entirely percutaneously invasively implanted system for use with an external light source. **Lee** is neither implanted or involves any fiber optic insertions.

Consider the amended claims in light of the above observations of the prior art. Claim 1 is directed to an apparatus for full invasive implantation in a body cavity having an inner surface for use with an external source of light to allow repeated, nontraumatic photodynamic treatments of a patient. **Dietrich** does not show an implantable, inflatable balloon which expands into the body cavity to prevent the inner surface of the body cavity from folding in on itself and to thus allow substantially all of the inner surface to be disposed in a direct line of sight to at least one point within an interior of the balloon. The **Dietrich** balloon only partially fills the bladder. None of the reference has any means for allowing repetitive nontraumatic access of an optical fiber to the body cavity over an extended period of time. None of the references show segregation of the optical fiber

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[1] The undersigned is intimately familiar with **Lee**, having written and prosecuted the **Lee** patent.

from the interior of the balloon. The claimed combination cannot be held inferable from references which do not teach or motivate the claimed features.

Claim 2 depends on claim 1 and is allowable on that ground as well as for the additional features or limitations set out in the claim.

Claim 4 adds the requirement of a light diffuser disposed on the distal end of the optical fiber. No such element is taught in **Dietrich, Chen** or **Lee**. The claimed combination cannot be held inferable from references which do not teach or motivate the claimed features.

Claim 6 calls for the means for allowing repetitive nontraumatic access to comprise an insert removably coupled to the proximal end of the catheter and to the first lumen in the catheter with a self-healing membrane supported in a proximal end of the insert. There is no such insert in **Dietrich**, **Chen** or **Lee,** and none of these references contemplate or make provisions for the repeated insertion of any instrument or optical fiber into a fully implanted percutaneous catheter. The claimed combination cannot be held inferable from references which do not teach or motivate the claimed features.

Claim 7 adds the element of a transparent plug disposed in the distal end of the first lumen of the catheter which also seals first lumen. There is no such transparent plug in **Dietrich**, **Chen** or **Lee.**

Claim 8 is directed to requiring a second lumen defined in the catheter for use to inflate the balloon. **Dietrich** fails to disclose whether optic fiber 6 is in the same in-flow/out-flow lumens 8, 8' of catheter 5 or in a separate lumen. Claim 8 depends on claim 1 and is allowable on that ground as well as for the additional features or limitations set out in the claim.

Claim 9 is directed to the addition of a valve for sealing the second lumen of the catheter to prevent deflation of the balloon. **Dietrich** fails to disclose any valving, but describes a continuous in-flow and out-flow. Claim 9 depends on claim 8 and is allowable on that ground as well as for the additional features or limitations set out in the claim.

Claim 10 defines the means for allowing repetitive nontraumatic access as a funnel shaped insert coupled to the first lumen in the catheter to ease in disposition of the insert into the patient and to facilitate introduction of the optical fiber therethrough without damage to the optical fiber. None of the references address the problem of repeated insertion of an optical fiber into a fully percutaneously implanted system.

Claim 11 requires that the insert snugly press fit into the lumen of the catheter. Claim 11 depends on claim 10 and is allowable on that ground as well as for the additional features or limitations set out in the claim..

Claim 15 adds an ambulatory laser and control circuit for repetitive, fractionated photodynamic treatment. None of the references show or discuss any such ambulatory pack to be carried by a patient so that treatments may occur at any place and any time regardless of the nature of the activity or even the intervention of the patient.

Claim 16 further adds a detector for recording dosage levels and history applied to the patient by the ambulatory laser and control circuit. None of the references disclose any detection and recording of dosage levels in an ambulatory, long term treatment system.

Claim 17 adds a radiation source disposable in the catheter for repetitive, fractionated radiation treatment in combination with fractionated photodynamic treatment through the catheter. **Hayman** is recognized as teaching the combination of PDT and

radiation treatments. However, **Hayman** does not disclose fractionated radiation treatment in combination with fractionated photodynamic treatment over an extended time as being a particularly efficacious treatment regimen as determined by the invention. **Dietrich**, **Chen** and **Lee** are devoid of any teaching regarding the combination of radiation and PDT in any form.

Claim 19 is direct to adding a subdermally implanted remote optical coupler for temporary optical coupling to the optical fiber, and a permanently implanted optical fiber communicating between the optical coupler and the balloon. None of the references disclose anything remotely relating to a two part optical fiber system as claimed.

Claim 21 requires the subdermally implanted remote optical coupler to comprise a transdermal optical connector. None of the references disclose anything relating to a two part optical fiber system as claimed.

Claims 22 – 31 and 33 – 40 were rejected as obvious over **Dietrich, Chen**, and **Lee**. Claim 22 is directed to a method of photodynamically, repetitively, nontraumatically treating a tumor resection characterized by a body cavity having an inner surface in a patient using an external light source in a fully subcutaneously implanted catheter and balloon system. The inflatable balloon is inflated in the body cavity by means of a first lumen defined in the catheter to prevent the inner surface of the body cavity from folding in on itself and to thus allow substantially all of the inner surface to be exposed by a direct line of sight to at least one point within the balloon. No such use of the balloon or teaching is disclosed by **Dietrich**. Then an optical fiber is repetitively disposed through at most the skin of the patient and through a second lumen defined in the catheter to position

a distal end of the optical fiber within the inflatable balloon. **Dietrich, Chen** and **L e** disclose no such step. A fractionated dosage of light from the external light source is delivered through the optical fiber to effectively photodynamically treat the tumor resection so that repetitive, but nontraumatic, photodynamic treatment is provided. No fractionated dosage is taught or discussed by **Dietrich, Chen** and **Lee** and these prior art technologies are incapable of delivering a repetitive, but nontraumatic, photodynamic treatment in an invasively implanted system. These claimed features go far beyond merely full implantation alone or breast cancer treatment as mentioned by the Examiner. The claimed combination cannot be held inferable from references which do not teach or motivate the claimed features.

The Examiner appears to maintain that the methodology of using the claimed system is obvious to routineer in the art, even where the claimed system was not previously known. The method of using a novel system to obtain a new treatment never before practiced, because no system for practicing it previously existed, must necessarily be novel itself. Ascertaining the level of ordinary skill is necessary to maintain objectivity. "The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). The Examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

Claim 23 requires the step of repetitively removing and reinserting the optical fiber from the catheter. None of the references address any methodology in which the optical fiber is removed from a catheter as part of the treatment,

Claim 24 requires the step of repeating the disposition of the optical fiber into the subcutaneous catheter and the delivering a dosage of light through the optical fiber to effectively photodynamically treat the tumor resection during treatments repeated over an extended period of time. None of the references address any methodology in which there is repeated treatments over an extended period of time involving multiple optic fiber insertions and irradiations.

Claim 25 requires that the extended period of time to be at least one month. This time duration places certain requirements on the system in which such optic fiber reinsertions must occur. None of the references address the problems or solutions to providing extended treatment systems or methods. Claim 25 depends on claim 24 and is allowable therewith and for the additional limitations claimed.

Claim 26 requires the extended period of time to be more than one year. This time duration places certain requirements on the system in which such optic fiber reinsertions must occur. None of the references address the problems or solutions to providing extended treatment systems or methods. Claim 26 depends on claim 24 and is allowable therewith and for the additional limitations claimed.

Claim 28 requires that the step of disposing an optical fiber through the subcutaneous catheter repetitively positions the optical fiber therein over an extended period of time during which a fractionated dosage of light is repetitively delivered. None of

the references address the problems or solutions to providing extended treatment systems or methods, let alone discuss fractionated dosages during such times.

Claim 29 depends on claim 28 and is analogous to claim 25 and is allowable for the same grounds.

Claim 30 depends on claim 28 and is analogous to claim 26 and is allowable for the same grounds.

Claim 31 depends on claim 22 and is analogous to claim 16 and is allowable for the same grounds.

Claim 32 depends on claim 22 and is analogous to claim 17 and is allowable for the same grounds.

Claim 33 depends on claim 22 and is analogous to claim 19 and is allowable for the same grounds.

Claim 34 requires the step of disposing the optical fiber through a remote access port to dispose the optical fiber to an optical coupler serving as the remote access port and having a permanent implanted optical fiber coupling the optical coupler to a light emission point positioned in the balloon. The step of repetitively delivering a fractionated dosage of light through the optical fiber is required to include the step of coupling an external optical fiber to the optical coupler and delivering the fractionated dosage of light through the external optical fiber to the optical coupler. None of the references are directed in any sense to either one of these requirements for among other reasons they do no contemplate the use of two part optical delivery systems or fractionated dosage.

Claim 37 adds the step of disposing the insert into a cranium and supporting the insert only by the cranium of the patient so that forces applied to the insert are prevented

from being transmitted to underlying brain tissue. None of the references addresses the implanting of inserts into the cranium or into bone tissue of any kind, let alone a system implanted into the brain.

Claim 40 is directed to fully implanting the catheter in a breast. While PDT beast treatment is known and mentioned in passing by **Chen**, none of the references suggest full implantation of a catheter into the breast. Further, claim 40 depends on claim 34 and is allowable therewith.

Claim 32 was rejected as obvious over **Dietrich, Chen**, and **Lee** in view of **Hayman**. Claim 32 is directed to adding the steps of disposing a radiation source through the subcutaneous catheter to position a distal end of the radiation source within the inflatable balloon, and repetitively delivering a fractionated dosage of radiation from the radiation source in combination with a repetitively delivered fractionated dosage of light through the optical fiber to effectively photodynamically treat the tumor resection. **Hayman** is recognized as suggesting the combination of PDT and radiation treatments. However, none of the references, including **Hayman,** disclose repetitively delivering a fractionated dosage of radiation with a repetitively delivered fractionated dosage of light as a particularly efficacious treatment of cancer.

The applicant respectively maintains that the amended claims are each directed to features which are not disclosed in, motivated by or inferable from any combination of the cited references. Advancement of the claims to issuance is respectfully requested.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on

December 3, 2002

By Nancy McElrath

Nancy McElrath 12-3-02

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V rsion With Markings To Show Changes Made

1. (twice amended) An apparatus for [placement] full invasive implantation in a body cavity having an inner surface [in a patient] for use with an external source of light to allow repeated, nontraumatic photodynamic treatments of a patient [, said apparatus] comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be [exposed] disposed in a direct line of sight to at least one point within an interior of said balloon;

an [subcutaneous,] implantable catheter coupled to said inflatable balloon for [percutant] fully percutaneous implantation [disposition] into said patient to access said body cavity, [said catheter arranged and configured to provide];

an optical fiber coupled to the external source of light; and

means for allowing repetitive nontraumatic access of the optical fiber to said body cavity over an extended period of time, [and having an] through a first lumen of the implantable catheter [to allow an optical fiber to be disposed through said first lumen] into said inflatable balloon while segregating the optical fiber [being segregated] from said interior of said balloon and [to] illuminat[e]ing said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface[, and having a second lumen for inflation of said balloon; and

wherein said subcutaneous catheter comprises a proximal end and a self-healing membrane coupled to and closing said proximal end].

4. (once amended) The apparatus of claim [3] 2 where said optical fiber has a distal end and further comprising a light diffuser disposed on said distal end of said optical fiber.

6. (twice amended) The apparatus of claim 1 [An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon;

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having a first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and]

wherein said subcutaneous catheter [comprises] has a proximal end and wherein the means for allowing repetitive nontraumatic access comprises an insert removably coupled to said proximal end, said insert having a distal end removably coupled to said

first lumen in said subcutaneous catheter and a self healing membrane supported in a proximal end of said insert, said self healing membrane sealingly closing the proximal insert for full [placement] subcutaneous[ly] implantation.

10. (twice amended) The apparatus of claim 1 [An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon; and

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having an first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and,] wherein[:] said subcutaneous catheter [comprises] has a proximal end and wherein the means for allowing repetitive nontraumatic access comprises an insert coupled to said proximal end, said insert is funnel shaped, said insert has a distal end coupled to said first lumen in said subcutaneous catheter and said funnel shape of said insert narrows down to where said insert is coupled to said lumen to ease in disposition of said insert into said

patient and to facilitate introduction of said optical fiber therethrough without damage to said optical fiber.

19. (twice amended) The apparatus of claim 1 [An apparatus for placement in a body cavity having an inner surface in a patient, said apparatus comprising:

an implantable, inflatable balloon for disposition into said body cavity and which when inflated expands into said body cavity to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within an interior of said balloon;

a subcutaneous, implantable catheter coupled to said inflatable balloon for percutant disposition into said patient to access said body cavity, said catheter arranged and configured to provide repetitive access to said body cavity over an extended period of time, and having a first lumen to allow an optical fiber to be disposed through said first lumen into said inflatable balloon while being segregated from said interior of said balloon and to illuminate said inner surface to provide repetitive photodynamic therapy to tissues adjacent to said inner surface, and having a second lumen for inflation of said balloon; and]

further comprising a subdermally implanted remote optical coupler for temporary optical coupling to the optical fiber, and a permanently implanted optical fiber communicating between said optical coupler and said balloon.

22. (twice amended) A method of photodynamically, repetitively, nontraumatically treating a tumor resection characterized by a body cavity having an inner surface in a patient using an external light source comprising:

selectively disposing and retaining a photosensitizing drug in cancerous tissue within said inner surface of said body cavity and adjacent thereto;

[closing off a proximal end of a subcutaneous catheter by a self sealing membrane;]

fully subcutaneously invasively implanting [said] a [subcutaneous] catheter so that both of a distal end and [said] a proximal end are under the skin of the patient;

[wherein said step of implanting comprises disposing] fully subcutaneously invasively implanting an inflatable balloon coupled to said distal end of said [subcutaneous] catheter into said body cavity;

inflating said inflatable balloon in said body cavity by means of a first lumen defined in said [subcutaneous] catheter to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed by a direct line of sight to at least one point within said balloon;

repetitively disposing an optical fiber through at most the skin of the patient and through a second lumen defined in said [subcutaneous] catheter to position a distal end of said optical fiber within said inflatable balloon; and

[repetitively] delivering a fractionated dosage of light from the external light source through said optical fiber to effectively photodynamically treat said tumor resection [by repetitively piercing the self sealing membrane in order to pass] when said distal end of said optical fiber is disposed through [to said distal end of the subcutaneous] the fully

subcutaneously implanted catheter so that repetitive but nontraumatic photodynamic treatment is provided.

23. (once amended) The method of claim 22 further comprising repetitively removing and reinserting said optical fiber from said subcutaneous catheter.

28. (once amended) The method of claim 22 where disposing an optical fiber through said subcutaneous catheter repetitively positions said optical fiber therein over an extended period of time during which [said] a fractionated dosage of light is repetitively delivered.

33. (once amended) The method of claim 22, further comprising providing a remote access port by implanting said proximal end of the [subcutaneous] catheter at a position remote from skin covering said recess, wherein disposing said optical fiber through said subcutaneous catheter comprises disposing said optical fiber through said implanted remote access port.

34. (twice amended) The method of claim 33 [A method of photodynamically treating a tumor resection characterized by a body cavity having an inner surface in a patient comprising:

selectively disposing and retaining a photosensitizing drug in cancerous tissue within said inner surface of said body cavity and adjacent thereto;

disposing an inflatable balloon into said body cavity coupled to a subcutaneous catheter;

inflating said inflatable balloon in said body cavity by means of a first lumen defined in said subcutaneous catheter to prevent said inner surface of said body cavity from folding in on itself and to thus allow substantially all of said inner surface to be exposed to at least one point within said balloon;

disposing an optical fiber through a second lumen defined in said subcutaneous catheter to position a distal end of said optical fiber within said inflatable balloon; and

repetitively delivering a fractionated dosage of light through said optical fiber to effectively photodynamically treat said tumor resection;

where disposing said optical fiber through said subcutaneous catheter comprises disposing said optical fiber through an implanted remote access port.]

wherein disposing said optical fiber through a remote access port disposes said optical fiber to an optical coupler serving as said remote access port and having a permanent implanted optical fiber coupling said optical coupler to a light emission point positioned in said balloon, and where repetitively delivering a fractionated dosage of light through said optical fiber comprises coupling an external optical fiber to said optical coupler and delivering said fractionated dosage of light through said external optical fiber to said optical coupler.

37. (once amended) The method of claim 22, wherein the catheter has a proximal end, and an insert is coupled to said proximal end; the method further comprising:

disposing said insert into a cranium and [supporing] supporting said insert only by said cranium of said patient[; and

supporting said insert by said cranium] so that forces applied to said insert are prevented from being transmitted to underlying brain tissue.

40. (once amended) The method of claim 34 where fully subcutaneously implanting the catheter [further comprising] comprises implanting said catheter in a breast [and entirely subcutaneously implanting the catheter].